


[illegible]

No new matter is presented by the above amendments. Early and favorable consideration of this application is respectfully requested.

Date: Nov. 23, 2001

Respectfully submitted,



Registration No. 31,674

ATTORNEY DOCKET NO. APV31160B

STEVENS, DAVIS, MILLER & MOSHER, L.L.P.  
1615 L STREET, N.W., SUITE 850  
WASHINGTON, D.C. 20036  
TEL. 202-785-0100 / FAX. 202-408-5200

ABSTRACT

Method and Device for Use in Micro-Invasive Surgical Procedures and Guide Catheter and Valve Unit for a Device for Use in Micro-Invasive Surgical Procedures

In a method and a device for use in micro-invasive surgical procedures, and a guide catheter and a valve unit for a device for use in micro-invasive surgical procedures, a bypass section (5) having an enlarged hydraulic cross section is provided, into which an instrument (10), for example a balloon, on an instrument catheter (11) can be retracted after treatment has been administered, thus allowing a sufficient quantity of fluid to flow past the instrument (1) and out of the guide catheter (4). By providing the bypass section (5) with an enlarged cross section, it becomes possible to use instruments (10) with very close-fitting guide catheters (4).

[ Fig. 1 ]

[illegible]

## for a Device for Use in Micro-Invasive Surgical Procedures

This claims priority under 35 USC § 119 from United States provisional patent applications serial number 60/253,749 filed November 29, 2000 and serial number 60/262,659 filed January 22, 2001, both incorporated herein by reference.

The invention relates to a method for use in micro-invasive surgical procedures, wherein an instrument catheter, which is fitted with an instrument, can be slid within a close-fitting guide catheter in the body of a patient, up to an area in which a diagnostic and/or therapeutic procedure is to be performed.

The invention further relates to a guide catheter for a device for use in micro-invasive surgical procedures, into which an instrument catheter, which is fitted with an instrument, can be inserted through a valve unit in the device.

A device of this type, a guide catheter of this type, and a valve unit of this type are known in the art, for example, from DE 198 23 064 C2. The state-of-the-art device is equipped with a valve unit that can be connected to a guide catheter, in which process a dilation catheter as the instrument catheter is inserted through the valve unit into the guide catheter along a guide wire. The dilation catheter is equipped with an expandable balloon as its instrument, which, after being

pushed out through the distal end of the guide catheter, can be used to treat vasoconstrictions via dilation. However, the known device, the known guide catheter, and the known valve unit that is used with a known device or a known guide catheter have the disadvantage that in order to permit a sufficient quantity of fluid, such as contrast medium for vasography, to pass through, the outer diameter of the guide catheter must be relatively large, and the outer diameter of the insertion valve must be increased accordingly, which results in a relatively high degree of trauma at the point of entry into a blood vessel.

### *Brief Summary of the Invention*

The object of the invention is to provide a method, a device, a guide catheter, and a valve unit of the type described at the beginning that will make it possible to introduce a sufficient quantity of fluid into the vascular region to be handled or treated in diagnostic or therapeutic micro-invasive surgical procedures, while the outer diameter of the guide catheter is kept relatively small.

This object is attained in accordance with the invention with a method of the type described above, in that during the micro-invasive surgical procedure, the instrument is positioned within a bypass section, whose hydraulic cross section is larger than the cross section of the guide catheter lumen, and whose length corresponds to at least the length of the instrument; and in that a fluid is introduced into the guide catheter along the instrument that is positioned within the bypass section.

This object is attained in accordance with the invention with a device, a guide catheter, and a valve unit of the type described at the beginning, in that a hydraulic bypass section is provided, wherein, while at least part of the guide catheter wall is close-fitting for the instrument, and the lumen cross section corresponds basically to the largest cross section of the instrument, the hydraulic cross section of the bypass section is larger than the lumen cross section, and its length corresponds to at least the length of the largest cross section of the instrument.

an instrument, designed to be a dilatable balloon. In this manner, the bypass section can be expanded when it is already inside the body of a patient, after being introduced through an insertion valve, which is relatively rigid, and whose size corresponds to the outer cross section of the guide catheter.

### *Brief Description of the Drawings*

Further advantageous embodiments and advantages of the invention are the object of the following description of exemplary embodiments, with reference to the figures in the diagrams.

These show:

Fig. 1        a partial side view cross section of a first exemplary embodiment of the invention having a bypass section that is positioned at the proximal end of a guide catheter;

Fig. 2        a partial side view cross section of a secondary exemplary embodiment of the invention, having a bypass section that is designed to form a single unit with a valve unit;

Fig. 3        a partial side view cross section of a third exemplary embodiment of the invention, having a bypass section that is designed as a separate intermediate segment;

Fig. 4        a partial side view cross section of a fourth exemplary embodiment of the invention, having a bypass section that is positioned in the distal end area of a guide catheter, and is equipped with a reinforcement structure;

Fig. 5        the exemplary embodiment as illustrated in Fig. 4, having a dilated balloon, positioned in the bypass section, as its instrument;

- Fig. 20 a section through the embodiment illustrated in Fig. 15 with the frame braces in their outward, disengaged, secondary position,
- Fig. 21 a section through the embodiment illustrated in Fig. 16 with the frame membrane in its outward, disengaged, secondary position,
- Fig. 22 a partial side view cross section of an eighth exemplary embodiment of the invention, with a section of a guide catheter having a pre-expanded bypass section, and
- Fig. 23 a lengthwise cross section of an insertion valve with a guide catheter that has already been introduced and has a pre-expanded bypass section.

### *Detailed Description*

Fig. 1 shows a first exemplary embodiment of the invention in a partial side view cross section. The device as illustrated in Fig. 1 is equipped with a valve unit 1, which in the initial exemplary embodiment is a state-of-the-art, so-called Y-valve. The valve unit 1 can be connected via a rotating coupling 2 to a proximal end 3 of a guide catheter 4 in the device. In the area of the proximal end 3 of the guide catheter 4, a bypass section 5, which has an enlarged hydraulic cross section, is positioned as the proximal end section 6 of the guide catheter 4. The guide catheter 4 can be inserted through a tissue wall 7 using an insertion valve 8, wherein, when the device is used as intended, a section 9 that is positioned inside the body has an inner diameter that is smaller than the inner diameter at the proximal end section 6 of the guide catheter 4. The device as illustrated in Fig. 1 is equipped with an expandable balloon 10 as a non-exclusive example of an instrument, which is connected via known means to an instrument catheter that is designed as a dilation catheter 11. The inner diameter of the inner-corporal section 9 corresponds generally to the outer diameter of the balloon 10, which is equipped with a guide wire 12 and a guide shaft 13 that is positioned at

ATTACHMENT IV - Marked up Amended Claims

1. (Amended) Device for use in micro-invasive surgical procedures, comprising a valve unit and a guide catheter that is connected to the valve unit, wherein an instrument catheter that is fitted with an instrument can be inserted through the valve unit into the guide catheter, [characterized in that] wherein a hydraulic bypass section (5) is provided, wherein, while at least part of the wall of the guide catheter (4) is close-fitting for the instrument (10), and the lumen cross section corresponds essentially to the largest cross section of the instrument (10), the hydraulic cross section of the bypass section is larger than the lumen cross section, and [its] the length of the bypass section corresponds to at least the length of the largest cross section of the instrument (10).

2. (Amended) Device in accordance with Claim 1, [characterized in that] wherein the bypass section (5) is integrated into the guide catheter (4).

3. (Amended) Device in accordance with Claim 2, [characterized in that] wherein the bypass section (5) is positioned in the area of the proximal end (3) of the guide catheter (4).

4. (Amended) Device in accordance with Claim 2, [characterized in that] wherein the bypass section (5) is positioned between the proximal end (3) and the distal end (15) of the guide catheter (4).

5. (Amended) Device in accordance with Claim 4, [characterized in that] wherein at least the bypass section (5) is designed to have a reinforcement structure (20).



6. (Amended) Device in accordance with Claim 5, [characterized in that] wherein the reinforcement structure (20) can be expanded in conjunction with the wall of the guide catheter (4), in the area of the bypass section (5).

7. (Amended) Device in accordance with [one of Claims 4 through 6] Claim 4, [characterized in that] wherein a radially flexible insertion valve (8) is provided.

8. (Amended) Device in accordance with Claim 4, [characterized in that] wherein the bypass section (5) is designed to have a bypass sheath (22) that encloses the guide catheter (4) and is connected to the wall of the guide catheter (4), being sealed at its edges; and to have recesses (23) that are built into the wall of the guide catheter (4), near the edges of the bypass sheath (22).

9. (Amended) Device in accordance with Claim 8, [characterized in that] wherein the recesses (23) are essentially rounded in cross section, or are rectangular in cross section, with the sides being essentially equal in length.

10. (Amended) Device in accordance with Claim 4, [characterized in that] wherein at least the bypass section (5) is designed to have a number of grooves (24) that extend through the wall of the guide catheter (4), wherein the grooves (24) are sealed by an outer sheath (25).

11. (Amended) Device in accordance with Claim 10, [characterized in that] wherein the grooves (24) are oriented lengthwise along the guide catheter (4).

12. (Amended) Device in accordance with Claim 10, [characterized in that] wherein the grooves (24) are designed to be coiled in a spiral.

13. (Amended) Device in accordance with Claim 4, [characterized in that] wherein the guide catheter (4) in the area of the bypass section (5) is equipped with a wall recess (25) that extends essentially over the entire length of the bypass section (5), and [in that] wherein a collapsible bypass sheath is attached to the wall of the guide catheter (4) and serves to seal the recess in the wall (25).

14. (Amended) Device in accordance with Claim 13, [characterized in that] wherein in the area of the wall recess (25) a sheath frame unit (26) is provided, which extends lengthwise along the guide catheter (4), and can be placed in an inward, engaged position or in an outward, disengaged position.

15. (Amended) Device in accordance with Claim 14, [characterized in that] wherein the sheath frame unit (26) is comprised of at least two frame braces (27), the outer surface area of which is small relative to the radial dimensions of the recess in the wall (25).

16. (Amended) Device in accordance with Claim 14, [characterized in that] wherein the sheath frame unit (25) is comprised of a frame membrane (28), the outer surface area of which is large relative to the radial dimensions of the recess in the wall (25).

17. (Amended) Device in accordance with [one of Claims 4 through 10] Claim 4, [characterized in that] wherein edge markers (21) are provided along the edges of the bypass section (5) for use in imaging procedures.

18. (Amended) Device in accordance with [one of Claims 4 through 16] Claim 4, [characterized in that] wherein visible or palpable markers are provided on the instrument

catheter (11), which can be seen or felt during positioning of the instrument (10) in the bypass section (5).

19. (Amended) Device in accordance with Claim 1, [characterized in that] wherein the bypass section (5) is designed to form a single piece with the valve unit (1).

20. (Amended) Device in accordance with Claim 1, [characterized in that] wherein the bypass section (5) is designed as an intermediate segment (18) that can be inserted between the guide catheter (4) and the valve unit (1).

21. (Amended) Device in accordance with Claim 20, [characterized in that] wherein the intermediate segment (18) can be connected to the guide catheter (4) such that it can rotate.

22. (Amended) Device in accordance with [one of Claims 3, 19, 20, or 21] Claim 3, [characterized in that] wherein the bypass section (5) is either entirely transparent, or transparent in at least one partial section.

23. (Amended) Device in accordance with [one of Claims 19 through 22] Claim 19, [characterized in that] wherein the length of the bypass section (5) and the length of the valve unit (1), into which the instrument catheter (11) is inserted, together correspond to at least the length of a section between the distal end (16) of the instrument (10) that slides along the guide wire, and a point of exit (14) for the guide wire (12) out of the guide shaft (13).

24. (Amended) Guide catheter for a device for use in micro-invasive surgical procedures, into which an instrument catheter that is fitted with an instrument can be

inserted through a valve unit in the device, [characterized in that] wherein a hydraulic bypass section (5) is provided, wherein, while at least part of the wall of the guide catheter (4) is close-fitting for the instrument (1), and the lumen cross section corresponds essentially to the largest cross section of the instrument (10), the hydraulic cross section of the bypass section is larger than the lumen cross section, and [its] the length of the bypass section corresponds to at least the length of the largest cross section of the instrument (10).

25. (Amended) Guide catheter in accordance with Claim 24, [characterized in that] wherein the bypass section (5) is positioned in the area of the proximal end (3) of the guide catheter (4).

26. (Amended) Guide catheter in accordance with Claim 24, [characterized in that] wherein the bypass section (5) is positioned between the proximal end (3) and the distal end (115) of the guide catheter (4).

27. (Amended) Guide catheter in accordance with Claim 26, [characterized in that] wherein at least the bypass section (5) is designed to have a reinforcement structure (20).

28. (Amended) Guide catheter in accordance with Claim 27, [characterized in that] wherein the reinforcement structure (20) can be expanded in conjunction with the wall of the guide catheter (4) in the area of the bypass section (5).

29. (Amended) Guide catheter in accordance with Claim 26, [characterized in that] wherein the bypass section (5) is designed to have a bypass sheath (22) that encloses the guide catheter (4) and is connected to the wall of the guide catheter (4), with its edges

being sealed, and to have recesses (23) built into the wall of the guide catheter (4) near the edges of the bypass sheath (22).

30. (Amended) Guide catheter in accordance with Claim 26, [characterized in that] wherein the recesses (23) are essentially round in cross section or rectangular in cross section, with the sides being essentially equal in length.

31. (Amended) Guide catheter in accordance with Claim 29, [characterized in that] wherein at least the bypass section (5) is designed to have a number of grooves (24) that extend through the wall of the guide catheter (4), wherein the grooves (24) are sealed by an outer sheath (25).

32. (Amended) Guide catheter in accordance with Claim 31, [characterized in that] wherein the grooves (24) are oriented lengthwise along the guide catheter (4).

33. (Amended) Guide catheter in accordance with Claim 31, [characterized in that] wherein the grooves (24) are designed to be coiled in a spiral.

34. (Amended) Guide catheter in accordance with Claim 26, [characterized in that] wherein the guide catheter (4) is designed to have a wall recess (25) in the area of the bypass section (5), that extends essentially over the entire length of the bypass section (5), and [in that] wherein a collapsible bypass sheath (22) is provided, which is attached to the wall recess (25) such that it forms a seal.

35. (Amended) Guide catheter in accordance with Claim 34, [characterized in that] wherein a sheath frame unit (26) is provided in the area of the wall recess (25),

extending lengthwise along the guide catheter, and can be placed in an inward, engaged position or in an outward, disengaged position.

36. (Amended) Guide catheter in accordance with Claim 35, [characterized in that] wherein the sheath frame unit (26) is comprised of at least two frame braces (27), the outer surface of which is small relative to the radial dimensions of the recess in the wall (25).

37. (Amended) Guide catheter in accordance with Claim 35, [characterized in that] wherein the sheath frame unit (25) is comprised of a frame membrane (28), the outer surface of which is large relative to the radial dimensions of the recess in the wall (25).

38. (Amended) Guide catheter in accordance with [one of Claims 26 through 37] Claim 26, [characterized in that] wherein edge markers (21) are provided along the edges of the bypass section (5) for use in imaging procedures.

39. (Amended) Valve unit for a device for use in micro-invasive surgical procedures that can be connected to a guide catheter, into which an instrument catheter, which is fitted with an instrument, can be inserted through the valve unit, [characterized in that] wherein a hydraulic bypass section (5) is provided, wherein, while at least part of the wall of the guide catheter (4) is close-fitting for the instrument (1), and the lumen cross section corresponds basically to the largest cross section of the instrument (10), the hydraulic cross section of the bypass section is larger than the lumen cross section, and [its] the length of the bypass section corresponds to at least the length of the largest cross section of the instrument (10).

40. (Amended) Valve unit in accordance with Claim 39, [characterized in that] wherein the bypass section (5) is designed to form a single unit with the valve unit (1).

41. (Amended) Valve unit in accordance with Claim 39, [characterized in that] wherein the bypass section (5) is designed as an intermediate segment (18) that is connected to the valve unit (1) such that it can be removed.

42. (Amended) Valve unit in accordance with Claim 41, [characterized in that] wherein the intermediate segment (18) can be connected to a guide catheter (4) such that it can rotate.

43. (Amended) Method for use in micro-invasive surgical procedures, wherein an instrument catheter (11) that is fitted with an instrument (10) can be inserted through a close-fitting guide catheter (4) in the body of a patient, until it reaches an area in which diagnostic and/or therapeutic procedures are to be performed, [characterized in that] wherein during the micro-invasive surgical procedure the instrument (10) is positioned inside a bypass section (5), whose hydraulic cross section is larger than the lumen cross section of the guide catheter (4), and whose length corresponds to at least the length of the instrument (10), and [in that] wherein when the instrument (10) has been positioned inside the bypass section (5), a fluid is introduced into the guide catheter (4).

44. (Amended) Method in accordance with Claim 43, [characterized in that] wherein the hydraulic cross section is expanded via an instrument, designed as a dilatable balloon (10).